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PATENT APPLICATION

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 via Label No. EV166727746US on October 2, 2002, addressed to Box: DAC, Commissioner for Patents, Washington, D.C. 20231.

Michael C. Houck  
Michael C. Houck, Paralegal

October 2, 2002  
Date Signed

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Shubh D. Sharma

Serial No. 09/483,837

Filed: January 17, 2000

For: Metallopeptide and Metallo-Constructs  
Combinatorial Libraries and Applications

Examiner: B. Celsa

Group Art Unit: 1627

#20

PETITION TO WITHDRAW HOLDING OF ABANDONMENT  
UNDER 37 C.F.R. § 1.181(a)

OR IN THE ALTERNATIVE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT  
ABANDONED  
UNINTENTIONALLY UNDER 37 C.F.R. § 1.137(b)

Box: DAC  
Commissioner for Patents  
Washington, D.C. 20231

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OCT 11 2002  
TECH CENTER 1600/2900

Dear Sir:

Applicant petitions from the Examiner's holding of abandonment pursuant to 37

C.F.R. § 1.181(a), requesting withdrawal of the holding of abandonment. Alternatively,

and in the event that the petition pursuant to 37 C.F.R. § 1.181(a) is not granted, Applicant petitions to revive the application pursuant to 37 C.F.R. § 1.137(b).

**Common Operative Facts.** The following are the common operative facts relevant to both petitions:

1. This application was filed January 17, 2000 and is a divisional application of Serial No. 08/660,697, filed 5 June 1996, now United States Patent No. 6,027,711. The specification is identical to that of United States Patent No. 6,331,285, also a divisional application of Serial No. 08/660,697, now United States Patent No. 6,027,711.
2. A Sequence Listing and Preliminary Amendment was filed on May 3, 2000.
3. An Election/Restriction Office Action was mailed December 12, 2000 (Paper 7), and was promptly responded to by Applicant.
4. An Office Action rejecting elected claims 41-59 was mailed January 14, 2001 (Paper 10), and a Response to Office Action, including new claims, was mailed by Applicant on July 16, 2001, including an appropriate Petition for Extension.
5. No substantive response has ever been interposed by the Patent Office with respect to the Response to Office Action mailed by Applicant on July 16, 2001.
6. On October 2, 2001, a "Non-Responsive Letter: Bonafide Attempt" (Paper 14) was mailed by the Office addressing perceived failure to comply with the sequence rules. The specific point raised in the Letter was that "the specification [sic] contains peptides which are not present in the submitted computer readable form (CRF) and do not contain sequence identifiers: see e.g. specification pages 5, 21, 42, 53, 70, 72, 73, 108 and 115."

7. On November 1, 2001, Applicant filed an Amendment to Sequence Disclosure Addressing each of the points raised in the October 2, 2001 Letter.

8. On March 4, 2002, a "Sequence Rule Letter: Non-Bonafide Attempt" (Paper 17) was mailed by the Office, wherein the sole concern or issue raised was that the "Other Information" description (item 223) was inadequate for certain of the disclosed sequences. The same issue was present in the original submission filed January 17, 2000, but was not raised prior to the March 4, 2002 letter. The January 17, 2000 sequence listing referred to the sequence as "protein" while the November 1, 2001 sequence listing referred to the sequences as "peptide."

9. On March 20, 2002, after the undersigned attorney had telephonically consulted with both the assigned Examiner and staff at the Sequence Help Desk, yet another Sequence Disclosure was filed by mailing on such date. Applicant specifically requested that "...if Examiner has identified any error, the Examiner is requested to so inform Applicant."

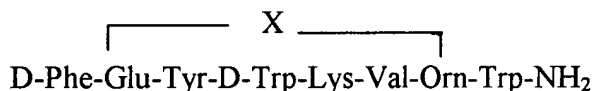
10. No further action was taken by the Office until August 2, 2002, when a Notice of Abandonment was mailed. The sole reason given was "Noncompliance with Sequence Rules within 6 months of Notice to comply letter dated 10/2/01: specification contains peptides (e.g. GGGH spec page 23; TKPR spec page 60) which are not part of sequence listing. See also "Sequence Rule Letter: Non-bona fide Attempt" mailed 3/4/02 in paper no. 17." In no previous communication was any issue raised with respect to GGGH or TKPR sequences.

**Petition Pursuant to 37 C.F.R. § 1.181(a).** The following operative facts are relevant to the petition pursuant to 37 C.F.R. § 1.181(a):

11. The Notice of Abandonment was the first and only time failure to comply based upon the sequence GGGH at page 23 of the specification or TKPR at page 60 of the specification was raised. The October 2, 2001 “Non-Responsive Letter: Bonafide Attempt” (Paper 14) listed specific pages for which a sequence listing was required. Neither page 23 nor page 60 was listed. The March 4, 2001 letter similarly did not list or raise page 23 or page 60.

12. The sequence GGGH is not, under any interpretation of the sequence rules, subject to the sequence rules. The relevant text at page 23 provides as follows:

The cyclic peptides of the general formula given immediately above include a somatostatin analogue of the formula:



wherein X contains L- or D- isomers of Gly-Gly-Gly-Cys, Gly-Gly-Cys, Gly-Gly-Gly-His, or Gly-Gly-His.

Specification, page 23, lines 18-23. This is thus a formula, wherein “Gly-Gly-Gly-His” (GGGH) is a part of “X”, and thus a part of the formula given. Rule 37 C.F.R. § 1.821(a) specifies that only “unbranched sequences” are covered by the rule. The formula given is a cyclic peptide (the lines indicate a cyclic structure, and thus is by definition branched at both the Glu and Orn residues). Further, 37 C.F.R. § 1.821(a)(2) specifies that “D-amino acids” are excluded. Two D-amino acids are present in the formula. Thus the amino acids GGGH are a part of a sequence given by the formula, which sequence is both branched and contains D-amino acids.

13. While literal compliance with the sequence rule may be contemplated by the rule, no claim at issue claims any of the sequences in the specification. The claims at issue are drawn solely to combinatorial libraries. There is no showing, and indeed could be no showing, that the sequence listing is relevant or material to examination of the claims. The sole issue is one of formal compliance, not affecting patentability. Entry of a notice of abandonment is inappropriate in such circumstances.

14. U.S. Patent No. 6,027,711 published with a sequence listing and as stated above is identical to the instant application. Pursuant to 37 C.F.R. § 1.821(e), the sequence listing from the other application may be transferred to the instant application. The sequence listing published with U.S. Patent No. 6,027,711 was accepted by the Patent Office without objection. Accordingly, transfer of the prior sequence listing, and withdrawal of the Notice of Abandonment, is appropriate. Given the acceptance by the Patent Office of sequence listings in cases with identical specifications, entry of a notice of abandonment is inappropriate.

15. With respect to the two letters issued by the Patent Office on the sequence listing, in each instance Applicant responded within one month. The delay by the Patent Office in considering Applicant's response was five months and four days in first instance (see numbered paragraphs 7 and 8 above) and approximately four and one-half months in the second instance (see numbered paragraphs 9 and 10 above). Fundamental fairness dictates that a holding of abandonment, given the promptness of response by Applicant and the length of time to respond by the Patent Office, be withdrawn. Failure, if at all, to respond within six months of the notice mailed October 2, 2001 is attributable to delays by the Patent Office, not Applicant.

16. The net effect is that the Examiner's letter of October 2, 2001, raised selected issues, but failed to raise issues subsequently raised in the March 4, 2002, letter or the August 2, 2002, Notice of Abandonment, even though such issues were present. The Examiner's letter of March 4, 2002, failed to raise issues subsequently raised for the first time in the August 2, 2002, Notice of Abandonment. Such piece meal advancement of "new" grounds, when such grounds existed at all relevant prior times, is fundamentally unfair and contrary to stated policies of the U.S. Patent and Trademark Office. See e.g., MPEP § 707.07(g).

17. Applicant at all times has earnestly attempted to comply with the sequence listing rules. Applicant specifically requested that any deficiency be brought to Applicant's attention.

**Petition Pursuant to 37 C.F.R. § 1.137(b).** The following operative facts are relevant to the petition pursuant to 37 C.F.R. § 1.137(b):

18. This application became abandoned on August 2, 2002, the date of mailing of the Notice of Abandonment.

19. This application became abandoned because the failure to prosecute was an unintentional delay. The entire delay in filing the required reply from the due date until the filing of this petition was unintentional.

20. A response, including a sequence listing, computer readable form, and verified statement that the computer readable form submitted in this amendment is the same as the "Sequence Listing" attached hereto.

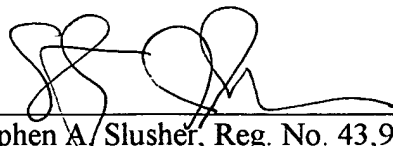
21. Applicant is a small business entity, and a fee of \$640 (37 CFR § 1.17(m)) is enclosed.

22. To the extent required authorization is hereby made to charge the amount of any fee due to Deposit Account No. 13-4213. A duplicate of this petition is attached.

Wherefore, Applicant requests that the Commissioner exercise his supervisory powers pursuant to 37 C.F.R. § 1.181(a), and withdraw the holding of abandonment. In the alternative, Applicant petitions for revival pursuant to 37 C.F.R. § 1.137(b).

Respectfully submitted,

Dated: October 2, 2002

By:   
Stephen A. Slusher, Reg. No. 43,924  
Direct line: (505) 998-6130

PEACOCK, MYERS & ADAMS, P.C.  
Attorneys for Applicant(s)  
P.O. BOX 26927  
Albuquerque, New Mexico 87125-6927  
Telephone: (505) 998-1500  
Facsimile: (505) 243-2542  
**Customer No. 005179**

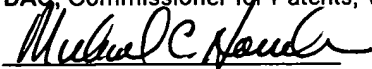


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Michael C. Houck, Paralegal

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OFFICE OF PETITIONS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Shubh D. Sharma  
Serial No. 09/483,837

Filed: January 17, 2000

For: Metallopeptide and Metallo-Constructs  
Combinatorial Libraries and Applications

Examiner: B. Celsa

Group Art Unit: 1627

**AMENDMENT TO SEQUENCE DISCLOSURE**  
**SUBMISSION OF "SEQUENCE LISTING" AND COMPUTER READABLE COPY, ARE THE**  
**SAME FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE AND/OR AMINO**  
**ACID SEQUENCE**  
**37 C.F.R. 1.821**

Box: DAC  
Non-Fee Amendments  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Applicant hereby states that each computer readable form submitted in this application amendment is the same as the "Sequence Listing" to which it is indicated to relate, and all papers accompanying this "Sequence Listing" submission, or for which a request for transfer from applicants' other application, introduce no new matter.

Respectfully submitted,

Dated: October 2, 2002

By:   
Stephen A. Slusher, Reg. No. 43,924  
Direct line: (505) 998-6130



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**Customer No. 005179**

File: 70024-9902  
G:\Mike\PATENT\Palatin-Rhomed\Div-II\SEQ List Amd2.decl2.doc[]



483837.ST25.txt  
SEQUENCE LISTING

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483837.ST25.txt

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Thr Lys Pro Arg

1



PATENT APPLICATION

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*Michael C. Houck*  
Michael C. Houck, Paralegal

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For: Metallopeptide and Metallo-Constructs :  
Combinatorial Libraries and Applications :

Examiner: B. Celsa

Group Art Unit: 1627

SECOND PRELIMINARY AMENDMENT

**Box: Non-Fee Amendments**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This is a supplemental amendment to Applicant's first preliminary amendment filed May 3, 2000. Please amend the above-identified application disclosure, without prejudice, as follows:

In the Specification:

Please amend the Specification by inclusion of the "Sequence Listing" disclosure which is separately submitted herewith and is concurrently submitted on diskette in accordance with the requirements of 37 C.F.R. § 1.821 et seq. In addition, please amend the Specification in the following aspects:

On page 23, line 22, after "Gly-Gly-Gly-His" insert --<SEQ ID NO:4>--.

On page 60, line 24, after "Thr-Lys-Pro-Arg" insert --<SEQ ID NO:11>--.

**REMARKS**

Submitted herewith is the "Sequence Listing" pursuant to 37 C.F.R. §§ 1.821 - 1.825. The submission includes no new matter which goes beyond the disclosure in the application as filed.

Submitted herewith is the paper copy of the "Sequence Listing" disclosure pursuant to 37 C.F.R. § 1.821(c). Submitted concurrently herewith is the computer readable copy of the same "Sequence Listing" disclosure pursuant to 37 C.F.R. § 1.824. Pursuant to 37 C.F.R. § 1.821(f), Applicant avers that the information recorded in computer readable form is identical to the written "Sequence Listing" and the required statement that the paper and computer readable copies are the same and include no new matter (37 CFR 1.821(g)).

In view of the above amendments and remarks, it is respectfully submitted that all grounds of objection to nucleotide sequence and/or amino acid sequence disclosures have been addressed. It is believed that the case is now in condition for examination and same is respectfully requested. Should the Examiner have any questions or comments the Examiner is invited to call the undersigned.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached paper is captioned "**Version with Markings to Show Changes Made.**"

Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213.

Respectfully submitted,

Dated: October 2, 2002

By:



Stephen A. Slusher, Reg. No. 43,924  
Direct line: (505) 998-6130

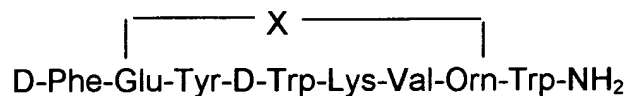
PEACOCK, MYERS & ADAMS, P.C.  
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Telephone: (505) 998-1500  
Facsimile: (505) 243-2542  
**Customer No. 005179**



**"Version with Markings to Show Changes Made"**

In the disclosure (page 23, line 22):

The cyclic peptides of the general formula given immediately above include a somatostatin analogue of the formula:



wherein X contains L- or D- isomers of Gly-Gly-Gly-Cys, Gly-Gly-Cys, Gly-Gly-Gly-His <SEQ ID NO:4>, or Gly-Gly-His.

In the disclosure (page 60, line 24):

Another example of a biological target-specific library of locally restricted metallopeptides constructed according to this invention are tuftsin mimetics. Tuftsin, the tetrapeptide Thr-Lys-Pro-Arg <SEQ ID NO:11>, is a natural stimulator of phagocytosis.

The basic criteria of this library of molecules are similarly a common rigid structural template formed by metal-peptide complexation, the presence of at least one amino acid suitably placed and known to have a high propensity to form a strong initial bond with a metal ion, and the presence of amino acids with side chains able to bind to the biological target receptor. One example, out of various general structures, includes:

$R_1$ -Aaa-Bbb-Ccc-Ddd-Eee- $R_2$  (for soluble libraries)